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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,895	04/09/2001	John K. Howard	57457-016	5554
20277	7590	02/12/2004	EXAMINER	
MCDERMOTT WILL & EMERY 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096			LUDLOW, JAN M	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,895

Applicant(s)

HOWARD, JOHN K.

Examiner

Jan M. Ludlow

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/9/2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1743

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mian et al (6319469).

Mian et al (6319469) teaches a disk having assay components on one side and conventional CD-RW media on the other (col. 8, lines 1-15). Disks the same size as commercial CDs are preferred (col. 8, lines 20-29). Figure 1C shows plural assay components around the outer portion of the disk. Figures 14A-F show the laser reading of the CD data towards the center of the disc. Erasable components are included (col. 27, line 16). Data on the disk can provide disk rotation speed (col. 20, lines 25-30) and other programming and assay performance instructions, identify the disk by serial number (instant unique code), and provide diagnostics, among other features (col. 28, lines 25-65). User information and acquired data are written to the disk, as are a history of procedures performed (col. 28, lines 41-65) and the history of events during a

Art Unit: 1743

procedure, such as valve status (col. 30, lines 30-35) or flow diagnostics (col. 31, lines 59-65). Patient identity can be input (col. 34, line 46). The set of analyses to be performed can be limited or exhaustive (col. 29, lines 11-16), suggesting that more than one type of assay is provided on the disk. The disk is used with a CD-ROM reader/player and CPU (e.g., Figure 15 and description thereof) to perform the method as claimed.

Mian fails to teach data in a continuous spiral track.

Kimura teaches that a CD conventionally has a spiral track (col. 3, lines 21-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to record the data of Mian in a continuous spiral track in order to provide conventional CD technology as taught by Mian, such conventional technology including a spiral track as taught by Kimura.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5. Zaffaroni additionally teaches assay wells on the outside edge of a disk and data bands on the inner edge (Figure 6A).

6. Applicant's arguments filed December 18, 2003 have been fully considered but they are not persuasive.

7. Applicant argues that Mian and Kimura do not specifically suggest using a continuous data band on an analytical disk. This argument is not persuasive because Mian repeatedly teaches using **conventional** CD technology, such as a compact disc or "Laservision" disc technology (col. 29, lines 2-5). The analytical disc is formed in the

Art Unit: 1743

manner of a **conventional** compact disc (CD) (col. 39, 36-37). Data is written using **conventional** optical data storage systems (col. 8, line 11). Kimura then teaches that the **conventional** CD format includes spiral (continuous) tracks. Thus, it would have been obvious to use spiral tracks in the device of Mian because Mian teaches using **conventional** CD technology and **conventional** CD technology is synonymous with spiral tracks as taught by Kimura. Applicant argues that the prior art assay devices use data sectors as taught by Virtanen, but Virtanen is not the basis of the rejection. Mian differs from Virtanen in that the optically readable CD portion is on the reverse side of the disc of Mian, separated from and unobstructed by the assay elements (e.g., col. 8, lines 6-15), whereas in Virtanen, the data and assay sectors are on the same side of the disc as shown in Figure 1. Thus, Virtanen is not the closest prior art, and the teachings of Virtanen are not seen as relevant to the rejection based on Mian.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

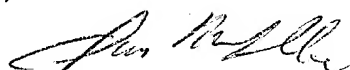
Art Unit: 1743

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
February 5, 2004